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Bifurcated Aortic Stent Grafts Are Safe and Effective for Endovascular Repair of Aortic Aneurysms in Patients With Narrow Distal Bifurcations: Aorto-Iliac Converters Are Rarely Needed in the Current Era

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Objectives: Endovascular aortic aneurysm repair (EVAR) in patients with narrow distal aortic bifurcations can be complicated by inability to access the contralateral gate, iliac limb compression, or aortic disruption. This study analyzes outcomes of EVAR using bifurcated stent grafts or aortouniiliac converters in patients with narrow distal aortic bifurcation.

Methods: We reviewed the clinical data of 1070 patients who underwent EVAR between 2000 and 2011. Digital computed tomographic angiography (CTA) was analyzed using centerline of flow measurements to determine aortic diameters. Patients with diameter ≤ 18 mm at the distal aortic bifurcation (AoB) were included in the study. End points were technical success, aortic disruption with retroperitoneal hemorrhage, stent graft complications (endoleaks, migration, sac enlargement, stenosis), reintervention, and iliac limb patency.

Results: There were 112 patients (84 men and 28 women; mean age, 75 years) with AoB ≤ 18 mm treated by EVAR, including 34 (30%) who had diameter of ≤ 14 mm. Mean outer and inner AoB diameter was 16 ± 3 and 14 ± 2 mm, respectively. Bifurcated stent grafts were used in 106 patients (95%). Six patients (5%) treated before 2005 had planned aortouniiliac converter with femoral crossover graft. The AoB was dilated after placement of bifurcated stent grafts using kissing balloon angioplasty in 80 patients (75%). All bifurcated stent grafts were successfully implanted, with no conversions to open repair or aortouniiliac converters. There was one early death (0.8%), and 12 patients (11%) developed early complications. There were no aortic disruptions or retroperitoneal hematomas. After a median follow-up of 34 months, 11 patients (11%) treated by bifurcated stent grafts required reintervention to treat endoleak ($n = 6$) or iliac limb stenosis/occlusion ($n = 5$). One patient (17%) treated by aortouniiliac converter required femoral crossover graft revision for restenosis. At 3 years, freedom from stent graft complication or reintervention was $91\% \pm 6\%$ and $91\% \pm 6\%$ for bifurcated stent grafts, and $83\% \pm 10\%$ and $83\% \pm 10\%$ for aortouniiliac converters ($P = NS$). Primary and secondary iliac limb patency was $98\% \pm 3\%$ and 100% for bifurcated stent grafts and $83\% \pm 10\%$ and 100% for aortouniiliac converters, respectively ($P = NS$).

Conclusions: Endovascular aortic aneurysm repair in patients with narrow distal aortic diameter is safe and effective using bifurcated stent grafts, even when the aortic bifurcation measures ≤ 14 mm. Using adjunctive balloon dilatation, there were no bleeding complications from aortic disruption, and limb patency was excellent. Aortouniiliac converters are rarely needed for this indication.

Intact Abdominal Aortic Aneurysm (AAA) Repair Is Not Appropriate in Patients on Dialysis

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Objectives: Abdominal aortic aneurysm (AAA) repair in the general population is effective, with reported mortality rates of $<10\%$ at 1 year. The outcomes of AAA repair in patients on dialysis are not well characterized, with a questionable survival advantage in such patients with limited life expectancy. The purpose of this study is to report the outcomes of AAA repair in United States dialysis patients.

Methods: The United States Renal Data System (USRDS) was used to collect data on intact asymptomatic AAA repair in all dialysis patients in the United States from the 2005 to 2008 Physician Services data files. Elective endovascular aneurysm repair (EVAR) and open repair were identified by CPT codes. Primary outcomes were the perioperative (30-day) mortality and long-term survival. Bivariate associations were tested using the χ^2 test, and predictors of mortality were identified using regression models.

Results: Of 2,260,986 dialysis patients, 1557 aged ≥ 30 years older had an AAA repair (0.05%); 261 open and 1296 EVAR (Table). The 30-day mortality was 11.5% (10.5% EVAR, 16.22% open, $P = .009$). The mortality rate 1 year after AAA repair was 39.0% (39.3% EVAR, 37.7% open; $P = .65$). Kaplan-Meier estimates of survival were 66.5% at 1 year (66.2% EVAR, 67.5% open; $P = .78$), and only 37.4% at 3 years (36.8% EVAR, 39.8% open; $P = .65$). Women had a higher overall mortality rate at 1 year (43.1%) than men (37.4%; $P = .06$). There was no significant 1-year mortality difference when comparing type of procedure in men (EVAR, 37.4%; open, 37.6%; $P = .95$) and in women (EVAR, 44.4%, open, 37.7%; $P = .31$). By logistic regression, older age in years (OR, 1.03; 95% CI, 1.02-1.05; $P < .001$), less time on dialysis in months (OR, 0.99; 95% CI, 0.981-1.00; $P < .001$), absence of a transplant (OR, 0.30; 95% CI, 0.20-0.45; $P < .001$), diabetes (OR, 1.75; 95% CI, 1.18-2.60, $P = .006$), absence of hypertension (OR, 0.54; 95% CI, 0.34-0.85; $P = .008$), and body mass index (OR, .96; 95% CI,

0.93-0.98; $P = .002$) had significant associations with mortality within the observation period.

Conclusions: AAA patients on dialysis have high perioperative and 1-year mortality rates after EVAR or open repair. This questions the indications for intact AAA repair in dialysis patients, especially in diabetic individuals, women, or older patients. AAA repair in dialysis patients may have to be restricted to patients with larger aneurysms, especially if open repair is required (Table).

Table. Comorbidities and risk factors by type of procedure

	Open repair N=261 N(%) ^a	EVAR N=1296 N(%) ^a	P value
Age (in years, mean \pm SD)	69.9 \pm 9.9	69.9 \pm 10.6	.99
Sex (M/F)	188 (72.0)/73 (30.0)	963 (74.3)/333(25.7)	.45
Hemodialysis/peritoneal dialysis	222 (94.5)/13 (5.5)	1091 (92.7)/86 (7.3)	.33
Diabetes	41 (25.6)	201 (25.2)	.89
History of transplant	42 (16.1)	260 (20.1)	.14
Ischemic heart disease	53 (33.1)	275 (34.4)	.76
CVA+TIA	17 (10.6)	84 (10.5)	.96
PVD	24 (15.0)	165 (20.6)	.10
Hypertension	128 (80.0)	655 (81.9)	.58
Smokers	16 (10.0)	71 (8.9)	.65
Presence of neoplasm	3 (1.9)	39 (4.9)	.09
Time on dialysis (in years, mean \pm SD)	4.2 \pm 2.5	4.5 \pm 3.0	.22
BMI (mean \pm SD)	25.9 \pm 5.9	26.6 \pm 5.9	.11

^aBecause of missing data, Ns vary considerably among rows.

One-Year Safety and Efficacy of Thoracic Aortic Stent Grafting (TEVAR) in Patients Who Are Poor Open Surgical Candidates: Results of the High-Risk Arm of the Valor Trial

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Objectives: The high-risk arm of the Valor trial was designed to include patients who are poor open surgical candidates, have an acute aortic dissection with malperfusion syndrome or impending aortic rupture, and traumatic aortic injuries. The 1-year results of this trial are reported.

Methods: This is a prospective, nonrandomized, multicenter trial designed to evaluate the safety and efficacy of TEVAR for several high-risk aortic pathologies. Primary end points included all-cause mortality and successful aneurysm exclusion at 30 days and 1 year. Secondary outcomes were freedom from major adverse events (MAE) and secondary procedures at 1 year.

Results: The study enrolled 137 patients, comprising 102 (75%) high-risk aneurysms, 18 (13%) dissections, and 17 (12%) traumatic injuries. Clinical factors include average age of 72 years, 58% male, 20% diabetic, 48% with coronary disease, and 46% symptomatic. The paraplegia rate was 0.7% (1 of 137) and the stroke rate was 9% (12 of 137), with no difference by etiology. The 30-day mortality was 7% (12% trauma, 6% aneurysm, 11% dissection), whereas the 1-year mortality rate was 25% (33% dissection, 25% aneurysm, 18% trauma). Predictors of all-cause mortality included cerebrovascular accident, paraplegia, and renal insufficiency. The 1-year aneurysm-related mortality was 11%; there were three aneurysm ruptures. Most deaths in the dissection cohort (5 of 6) were aneurysm related. Secondary procedures were performed in 14 patients (10%); 86% (12 of 14) were for endoleak. MAE occurred in 88 patients (64%) at 1 year, with 86% occurring in the first 30 days.

Conclusions: TEVAR can be accomplished with low mortality and paraplegia in patients who are poor open surgical candidates. MAEs are frequent, and the 1-year aneurysm-related death rate remains 11% in this high-risk population.

Relative Importance of Aneurysm Diameter and Body Size for Predicting AAA Rupture in Men and Women

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Objectives: Women have an increased risk of abdominal aortic aneurysm (AAA) rupture at any given aneurysm diameter compared with men. The accepted 5.5-cm repair threshold was derived from natural history studies based primarily on men. We evaluated the relationship between

rupture and aneurysm diameter relative to body size for men and women with the goal of testing a novel method of rupture risk stratification that is more appropriate for women.

Methods: We reviewed all patients in the Vascular Surgery Group of New England database who underwent endovascular or open AAA repair. We evaluated height, weight, body mass index (BMI), and body surface area (BSA) as well as each of these values indexed to the aortic diameter (eg, BSA index = aneurysm diameter (cm)/BSA [m²]). Along with other relevant clinical variables, we constructed multivariable-adjusted logistic regression models using forward selection to determine predictors of rupture repair vs elective repair. Models for men and women were developed separately, and different models were compared using the area under the curve (AUC).

Results: We identified 4045 patients who underwent AAA repair (11% ruptured, 53% EVAR, 78% men). Women had significantly smaller diameter aneurysms, lower BSA, and higher BSA indices than men (Table). For men, the primary determinant of rupture was aneurysm diameter (AUC, 0.82): <55 mm (referent); 55-64 mm (OR, 0.9; 95% CI, 0.5-1.7; *P* = .771); 65-74 mm (OR, 3.9; 95% CI, 1.9-1.0; *P* < .001); and ≥75 mm (OR, 11.3; 95% CI, 4.9-25.8; *P* < .001). In contrast, BSA index was most predictive of rupture for women (AUC, 0.81), with higher odds of rupture at higher BSA indices: <25 (OR, 3.9; 95% CI, 0.5-28.2; *P* = .175); 25-29 (OR, 3.3; 95% CI, 0.8-14.5; *P* = .111); 30-34 (referent); 35-39 (OR, 6.4; 95% CI, 1.7-24.1; *P* = .006); and ≥40 (OR, 9.5; 95% CI, 2.3-39.4; *P* = .002). For women, aneurysm diameter alone was not a significant predictor of rupture after adjusting for BSA index.

Conclusions: Aneurysm diameter indexed to body size is the most important determinant of rupture for women, whereas aneurysm diameter alone is most predictive of rupture for men. Women with the largest diameter aneurysms and the smallest body sizes are at the greatest risk of rupture.

Table. Demographics and multivariable predictors of ruptured repair

<i>Variables</i>	<i>Men</i> <i>(n = 3138)</i>	<i>Women</i> <i>(n = 907)</i>	P	
Demographics				
Age, mean (SD) years	71.9 (8.7)	74.3 (7.7)	<.001	
Aneurysm diameter, mm			<.001	
20-54, No. (%)	1032 (32.9)	368 (40.6)		
55-64, No. (%)	1170 (37.3)	350 (38.6)		
65-74, No. (%)	452 (14.4)	111 (12.2)		
≥75, No. (%)	483 (15.4)	78 (8.6)		
BSA, m ^{2a}			<.001	
<1.8, No. (%)	405 (12.9)	551 (60.7)		
1.8-1.9, No. (%)	1073 (34.2)	258 (28.5)		
≥2.0, No. (%)	1660 (52.9)	98 (10.8)		
BSA index, cm/m ^{2b}			<.001	
<25, No. (%)	668 (21.3)	77 (8.5)		
25-29, No. (%)	1136 (36.2)	231 (25.5)		
30-34, No. (%)	678 (21.6)	297 (32.7)		
35-39, No. (%)	342 (10.9)	171 (18.8)		
≥40, No. (%)	314 (10.0)	132 (14.5)		
<i>Predictors of ruptured repair</i>				
	<i>OR (95% CI)^c</i>	P	<i>OR (95% CI)^d</i>	P
Aneurysm diameter, mm				
20-54, %	1.0		1.0	
55-64, %	0.9 (0.5-1.7)	.8	1.1 (0.3-3.7)	.85
65-74, %	3.9 (1.9-8.0)	<.01	3.3 (0.8-12.7)	.09
≥75, %	11.3 (4.9-25.8)	<.01	3.2 (0.7-14.5)	.13
BSA Index, cm/m^{2b}				
<25, %	0.6 (0.3-1.4)	.23	3.9 (0.5-28.2)	.18
25-29, %	0.8 (0.5-1.5)	.53	3.3 (0.8-14.5)	.11
30-34, %	1.0		1.0	
35-39, %	0.8 (0.5-1.4)	.52	6.4 (1.7-24.1)	<.01
≥40, %	1.4 (0.8-2.6)	.2	9.5 (2.3-39.4)	<.01

^aBSA = BSA (m²) = 0.20247 × Height (m)^{0.725} × Weight (kg)^{0.425}.

^bBSA index = aneurysm diameter (cm)/BSA (m²).

^cArea under the curve = 0.82.

^dArea under the curve = 0.81.

A 20-Year Experience With Endovascular Repair of Abdominal Aortic Aneurysms: A Record of the Development and Evolution of Techniques, Devices, and Strategies

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Objectives: Endovascular repair of abdominal aortic aneurysms (EVAR) has become the first-line treatment of abdominal aortic aneurysms (AAA) worldwide. Since the first successful EVAR in North America, the authors have maintained a continuous, prospective database recording the details of each procedure.

Methods: Between 1992 and 2012, 1268 patients (mean age, 75 years; 85% men) underwent EVAR for repair of AAA. Fifteen different types of stent grafts were used (Table). Eighty-one percent of patients exhibited high-risk characteristics that would preclude participation in Food and Drug Administration-mandated, industry sponsored-IDE pivotal trials. Ninety-three percent of patients had at least one severe comorbid medical condition, with an average of 2.2 conditions per patient. During EVAR, 38% had concomitant treatment of associated common iliac artery aneurysms. Mean follow-up was 38.2 months.

Results: Major perioperative complications occurred in 7.5%, with a perioperative mortality rate of 2.5%. Aneurysm size remained stable or decreased (>5 mm) in 86.5% of patients and increased (>5 mm) in 13.5%; median time to aneurysm expansion was 8.2 years. During follow-up, type I endoleak occurred in 2.1% of patients and type III in 0.2%. Reintervention was required in 21% of patients. Mean time to reintervention was 26 months. Freedom from aneurysm-related mortality was 91.1% at 12 years. Median survival for all-cause mortality was 5.6 years.

Conclusions: Progressive advances in EVAR allow safe, effective, and durable repair of AAA, extending the instructions for use parameters of commercially available devices.

Table 1. Operative data

	Mean ± SD	
Anesthesia time (hours)	5.05 ± 1.51	
Surgery time (hours)	3.70 ± 1.47	
Estimated blood loss (mL)	367.8 ± 515.3	
Transfusion volume (mL)	645.3 ± 647.4	
Length of hospitalization (days)	2.75 ± 5.96	
Initial aneurysm size (cm)	5.9 ± 1.2	
Aneurysm size at latest F/U (cm)	5.5 ± 1.6	
	No. of patients	%
Pre-operative adjunctive procedure(s)	438	34.6%
Patients receiving transfusion	181	14.3%
General anesthesia	75	5.9%
Spinal or epidural anesthesia	1085	85.8%
Tube graft	59	4.7%
Bifurcated graft	992	78.2%
Aorto-uni-iliac graft	207	16.3%
Physician-made EVSGs	109	8.6%
Industry-made EVSGs	1159	91.4%
Discharge on postoperative day 0 or 1	802	63.4%
Major perioperative complications	95	7.5%
Perioperative mortality	32	2.5%

The Incidence of Contralateral Iliac Venous Thrombosis After Stenting Across the Iliocaval Confluence in Patients With Acute or Chronic Venous Outflow Obstruction

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Objectives: Percutaneous transluminal angioplasty and stenting of the iliac veins is becoming a more common method of treating patients with symptomatic lower extremity venous outflow obstruction. Several questions about the conformation of these stents remain to be answered. One, in particular, is whether these venous stents should extend into the vena cava or stop short of this in fear of causing further harm to the patient's contralateral leg.

Methods: We retrospectively reviewed prospectively collected data from 2008 to 2012 in patients with symptomatic ilio caval venous thrombosis who underwent percutaneous angioplasty and stenting. Data were collected using the AVF venous stent database variables. Most patients were maintained on full anticoagulation using warfarin (international normalized ratio 2-3) or low-molecular-weight heparin (weight-based daily or b.i.d. dosing). Patients with first time deep venous thrombosis were anticoagulated for 6 months on average, and those with repeat deep venous thrombosis were maintained on lifelong anticoagulation. Intraoperative anticoagulation was performed using intravenous heparin. Contralateral thrombosis and patency rates were recorded.

Results: A total of 183 ilio caval stents were placed in 66 patients (median age, 43; range 15-80 years), of which 63 patients experienced thrombosis causing the venous outflow obstruction. Thirty patients experienced acute venous thrombosis, 25 chronic, and nine acute on chronic. Forty-eight of 66 patients (72.7%) had patent stents noted on duplex